IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI, on behalf of itself, its physicians and staff, and its patients; MEMPHIS CENTER FOR REPRODUCTIVE HEALTH, on behalf of itself, its physicians and staff, and its patients; KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH, on behalf of itself, its physicians and staff, and its patients; FEMHEALTH USA, INC., d/b/a CARAFEM, on behalf of itself, its physicians and staff, and its patients; and AUDREY LANCE, M.D., M.S., on behalf of herself and her patients,

Plaintiffs,

v.

HERBERT H. SLATERY III, Attorney General of Tennessee, in his official capacity; LISA PIERCEY, M.D., Commissioner of the Tennessee Department of Health, in her official capacity; RENE SAUNDERS, M.D., Chair of the Board for Licensing Health Care Facilities, in her official capacity; W. REEVES JOHNSON, JR.,M.D., President of the Tennessee Board of Medical Examiners, in his official capacity; AMY P. WEIRICH, District Attorney General of Shelby County, Tennessee, in her official capacity; GLENN FUNK, District Attorney General of Davidson County, Tennessee, in his official capacity; CHARME P. ALLEN, District Attorney General of Knox County, Tennessee, in her official capacity; and TOM P. THOMPSON, JR., District Attorney General for Wilson County, Tennessee, in his official capacity,

Defendants.

CIVIL ACTION
CASE NO. 3:20-cv-00740
JUDGE CAMPBELL

RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

Defendants Herbert H. Slatery III, Lisa Piercey, Rene Saunders, W. Reeves Johnson, Jr., Amy P. Weirich, Glenn Funk, Charme P. Allen, and Tom P. Thompson, Jr., in their official capacities only, oppose Plaintiffs' Motion for a Temporary Restraining Order and/or Preliminary Injunction. (D.E. 6). The Motion should be denied because Plaintiffs have not carried their heavy burden to establish an entitlement to the "extraordinary and drastic remedy" of preliminary relief. *Enchant Christmas Light Maze & Market Ltd. v. Glowco, LLC*, 958 F.3d 532, 539 (6th Cir. 2020) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1977)).

BACKGROUND

On June 19, 2020, the General Assembly passed House Bill 2263/Senate Bill 2196 ("the Act") by overwhelming majorities in both Houses to further the State's interests in protecting and respecting the life of unborn children, protecting maternal health, preventing fetal pain, protecting the integrity of the medical profession, promoting human dignity, and preventing discrimination. *See* Tenn. Code Ann. §§ 39-15-214 to -218. Plaintiffs seek to enjoin the enforcement of the informed-consent provision, Tenn. Code Ann. § 39-15-218, which will take effect on October 1, 2020.

A. Legislative History

The informed-consent provision requires abortion providers to give patients more information about "chemical abortion," defined as "the use or prescription of an abortion-inducing drug dispensed with intent to cause the death of the unborn child." Tenn. Code Ann. § 39-15-218(a)(2). Specifically, the informed-consent provision requires "a private office, ambulatory surgical treatment center, facility, or clinic" that has performed more than 50 elective abortions during the previous calendar year to "conspicuously post a sign" that contains the following message:

> Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately.

Id. § 39-15-218(b). This sign "must be printed with lettering that is legible and at least three quarters of an inch (0.75″) boldfaced type." *Id.* § 39-15-218(c). Private offices and ambulatory surgical treatment centers must post the sign "in each patient waiting room and patient consultation room used by patients on whom abortions are performed." *Id.* § 39-15-218(d). And hospitals and other facilities must post the sign "in each patient admission area used by patients on whom abortions are performed." *Id.*

The informed-consent provision also prohibits a physician from performing a chemical abortion involving the use of mifepristone and misoprostol unless the physician has informed the patient at least 48 hours in advance that "(1) It may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind, but that time is of the essence; and (2) Information on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website." *Id.* § 39-15-218(e). This requirement is subject to a medical emergency exception. *Id.*

Additionally, once a physician has administered mifepristone, the physician or an agent of the physician must provide the patient with "written medical discharge instructions" that include the following statement:

> Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately.

Id. § 39-15-218(f).

The informed-consent provision also directs the Tennessee Department of Health to

"develop and maintain a stable internet website" that will provide materials "designed to inform the woman of the possibility of reversing the effects of a chemical abortion utilizing mifepristone if the woman changes her mind and information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion." *Id.* § 39-15-218(h)–(i).

"Any person who knowingly or recklessly performs or induces or attempts to perform or induce an abortion in violation of [Section 218] commits a Class E felony." *Id.* § 39-15-218(j). Abortion providers that negligently fail to comply with the informed-consent provision are subject to a civil penalty of $10,000 for each day that an abortion is performed during the period of noncompliance. *Id.* § 39-15-218(k). Physicians who perform a chemical abortion without complying with the informed-consent provision are subject to actual and punitive damages in an action brought by the patient, the father, or a parent of a minor patient or a deceased patient. *Id.* § 39-15-218(l).

The General Assembly enacted this informed-consent provision after hearing extensive expert medical testimony about medication abortion and a treatment sometimes referred to as "abortion pill reversal." On March 10, 2020, Dr. Brent Boles, a practicing OB/GYN in Murfreesboro, Tennessee, testified in favor of the proposed legislation at a House Health Committee hearing. (Ex. A, Boles Decl., Attachment 2, Legislative History.) He explained that a medication abortion involves taking two pills—Mifeprex (mifepristone) and Cytotec (misoprostol). (*Id*. at 5.) The first pill, mifepristone, is a "progesterone blocker," which "will cause the loss of the embryo or the fetal life." (*Id.* at 5.) The second pill, misoprostol, is taken between 24 and 48 hours after the first pill to "ensure that the tissue is expelled." (*Id.* at pp. 5–6.) Dr. Boles told the committee that "[b]asic princip[le]s of pharmacology have led us to discover that when a patient has changed her mind and has taken the mifepristone but has not yet taken the

Cytotec, that if you simply administer natural progesterone, you have as high as a 68 percent success rate in preventing loss of the fetal life." (*Id*. at 6.)

According to Dr. Boles, the use of progesterone to counteract the effects of mifepristone dates back to 2007, when Dr. Matthew Harrison helped a South Carolina woman rescue her pregnancy from an attempted medical abortion. (*Id.* at 6.) In 2012, Dr. George Delgado published a small case series that involved six women who attempted to save their pregnancies by taking progesterone. (*Id.* at 6–7.) Four of the six women successfully rescued their pregnancies. (*Id.* at 7.) In 2018, Dr. Delgado conducted a much larger study involving 754 patients. (*Id*. at 7.) In this study, patients who were prescribed progesterone after taking mifepristone had a 68% success rate at saving their pregnancies, "with no increased outcomes that were unfavorable for the mother or the baby." (*Id.* at 7.)

Dr. Boles explained that pro-abortion groups, like ACOG, often cite to a 2019 study by Dr. Creinin to support their position that progesterone is neither safe nor effective at saving a pregnancy from an attempted medication abortion. (*Id*. at 8.) Dr. Boles noted that this study only involved 12 patients, two of which dropped out of the study altogether. (*Id.* at 8–9.) Of the ten remaining patients, three had severe adverse reactions. (*Id*. at 8–9.) Importantly, however, two of those three patients took mifepristone and a placebo. (*Id*. at 8–9.) Only one patient who took progesterone had an adverse reaction. (*Id*. at 9.)

Dr. Boles also testified about his involvement with the Abortion Pill Reversal network. (*Id.* at 4, 14, 27.) The organization maintains a 24/7 hotline which connects women to one of more than 500 local practitioners who are willing to prescribe progesterone to women who have initiated the medical abortion process. (*Id*. at 14.) Dr. Boles told the committee that the network had helped more than 1,000 women save their pregnancies. (*Id*. at 14.) In fact, he explained that about

two weeks prior to the committee hearing, he had talked to a woman who called the hotline "begging for help less than an hour after taking the first pill in the series." (*Id.* at 27.) Dr. Boles said the hotline gets "at least a dozen phone calls a day[.]" (*Id*. at 27.)

Dr. Nikki Zite, a practicing OB/GYN in Knoxville, Tennessee, and a member of ACOG, testified against the proposed legislation at a House Public Health Subcommittee hearing. *Hearing on H.B. 2568 Before the House Public Health Subcommittee*, 111th General Assembly (Feb. 25, 2020) (statement and questioning of Dr. Nikki Zite) (04:39-19:06), http://tnga.granicus.com/MediaPlayer.php?view_id=414&clip_id=21848. Dr. Zite told the committee that ACOG does not support the legislation because "medication abortion reversal is not supported by science." *Id.* at 05:31. She criticized Dr. Delgado's 2012 study because of its small sample size, but Dr. Zite then relied on Dr. Creinin's 2019 study of just 12 patients to argue that it is not safe for women to use progesterone after initiating a medication abortion. *Id.* at 05:31, 06:25. Dr. Zite did not mention the larger study Dr. Delgado conducted in 2018. *See generally id.* Dr. Zite also admitted that as many as half of women who take mifepristone alone are not successful in terminating their pregnancies. *Id.* at 11:40.

B. Medication Abortion

Medication abortions are available during the first 10 weeks of pregnancy.[1] The most common form of medication abortion involves the use of two drugs—mifepristone (Mifeprex) and misoprostol (Cytotec). (FDA Mifeprex Label, at 2.) The first drug, mifepristone, is taken orally in the presence of an abortion provider. (FDA Mifeprex Label, at 3.) The purpose of mifepristone is to cause embryonic death by "block[ing] the action of a natural pregnancy hormone called

[1] MIFEPREX (Mifepristone) Tablets Label, FDA, at 2, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (2016) (hereinafter, FDA Mifeprex Label).

progesterone[.]" (Ex. B, Harrison Decl., ¶ 8.) The second drug, misoprostol, is taken buccally between 24 and 48 hours later. (FDA Mifeprex Label, at 3.) This drug ensures fetal demise by causing the uterus to contract and expelling its contents. (Ex. B, Harrison Decl., ¶ 8.)

The FDA strictly regulates medication abortions. To obtain a patient's informed consent, the FDA requires medication-abortion providers to "[i]nform the patient that uterine bleeding and uterine cramping will occur" and to "[a]dvise the patient that serious and sometimes fatal infections and bleeding can occur very rarely." (FDA Mifeprex Label, at 14.) Patients seeking a medication abortion must sign a "Patient Agreement Form." (FDA Mifeprex Label, at 14.) Medication abortion is also "only available in clinics, medical offices and hospitals" that are certified through a restricted program called the MIFEPREX REMS Program. (FDA Mifeprex Label, at 14.)

C. Effects of Taking Mifepristone Alone

It is undisputed that taking mifepristone alone is not always effective at ending a pregnancy. In their Complaint, Plaintiffs admit that "[m]edication abortion is more effective when both mifepristone and misoprostol are used together because *mifepristone alone will not always cause an abortion*." (D.E. 1, PageID# 19.) (emphasis added). A similar admission appears on Planned Parenthood's website: "Studies on the abortion pill do show that if you take the first medicine but not the second, the abortion pill is less likely to work." (Ex. C, Dunne Decl.) Dr. Daniel Grossman, an abortion provider, surveyed 13 different studies and found that between 8% and 46% of pregnancies will continue when only mifepristone is administered. (*See* Schreiber Decl., D.E. 6-1, PageID# 179; *see also* Ex. A, Boles Decl., ¶ 6; Ex. B, Harrison Decl., ¶ 9; Ex. D, Delgado Decl., ¶ 24.)

D. The Use of Progesterone to Counteract Mifepristone.

Where a patient chooses to try to save her pregnancy after taking mifepristone, studies and experience indicate that progesterone can be used to increase the chances of fetal survival. The use of progesterone to reverse the effects of mifepristone and thus halt medical abortion is based on basic science, animal studies and studies of humans. (*See generally* Ex. B, Harrison Decl., at ¶¶ 8-32; Ex. D, Delgado Decl., at ¶¶ 17-24; Ex. A, Boles Decl., at ¶¶ 8-14.)

Mifepristone disrupts the natural biological functioning of pregnancy by fatally disrupting the development of the embryo by blocking progesterone, which builds and maintains the uterine wall during pregnancy, preventing an embryo from implanting, receiving nutrition, and continuing to develop. Since Mifepristone starves the fetus of progesterone, supplemental progesterone competitively inhibits the mifepristone to prevent the induced abortion. But after a patient uses mifepristone and changes her mind, the patient needs the progesterone supplemented as soon as possible. (*See generally* Ex. B, Harrison Decl., at ¶¶ 8, 13-20; Ex. D, Delgado Decl., at ¶¶ 10-17.)

Published studies support the efficacy of progesterone treatment. (*See generally* Ex. B, Harrison Decl., at ¶¶ 21-28; Ex. D, Delgado Decl., at ¶¶ 19-24; Ex. A, Boles Decl., at ¶¶ 12-14.) For example, in 2018, Dr. George Delgado published "A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone" in the peer-reviewed publication *Issues in Law & Medicine*. (Ex. E, Delgado 2018 Study). This study involved 754 patients who decided to attempt to reverse the medication abortion process after taking mifepristone but before taking misoprostol. (*Id.* at 21.) "After exclusions, there were 547 patients with analyzable outcomes who underwent progesterone therapy." (*Id.* at 26.) Patients who "received oral progesterone, 400 mg twice a day for three days, followed by 400 mg once a day until the end of the first trimester and had a reversal rate of 68%[.]" (*Id.*) There was no increased risk for birth defects. (*Id.*) The preterm delivery rate was only 2.7%, well below the national average of 10%.

(*Id.*)

While Plaintiffs decry the use of progesterone in this context as radical and experimental, "the logic and feasibility" of using progesterone to reverse the intended effects of mifepristone "was not conjured out of thin air." (Ex. B, Harrison Decl., at ¶¶ 12-13.) It is "a basic principle of biochemistry" that "competitive inhibitors (like mifepristone) that replace and block out substrates (like natural progesterone) may be thwarted if there is enough substrate around." (*Id.* at ¶ 13.) For example, methotrexate is a drug given to kill cancer cells. (*Id.* at ¶ 15.) But because the drug can also kill non-cancer cells, doctors will prescribe leucovorin "to out-compete" the methotrexate and 'rescue' the non-cancer cells." (*Id.*) Progesterone supplementation has also been used therapeutically since the 1970s to counter infertility and recurrent miscarriage. (Ex. D, Delgado Decl., at ¶ 23.) Critics, such as through the unsuccessful 2019 Creinin study, have failed to demonstrate scientifically that progesterone treatment cannot work. (*See generally* Ex. B, Harrison Decl., at ¶¶ 33-47; Ex. D, Delgado Decl., at ¶¶ 25-37; Ex. A, Boles Decl., at ¶ 15.)

And experience shows that natural progesterone is safe for mother and baby. (*See generally* Ex. B, Harrison Decl., at ¶¶ 28-31; Ex. D, Delgado Decl., at ¶¶ 21-23; Ex. A, Boles Decl., at ¶¶ 9-14.). The FDA has considered it free from risk of birth defects since 1999. And the American Society for Reproductive Medicine similarly determined that:

> The weight of available evidence suggests that progesterone supplementation in early pregnancy poses no significant risk to mother or fetus . . . Controlled studies show no increase in congenital anomalies, including genital abnormalities in male or female infants, resulting from maternal exposure to [progesterone] . . .during early pregnancy.

ASRM Bulletin November, 2008 Volume 90, Issue 5, Supplement, Pages S150–S153. The Abortion Pill Rescue Network has documented over 1,000 successful medication abortion reversals, including some within Tennessee, following this progesterone treatment. (*See generally*

Ex. D, Delgado Decl., at ¶¶ 39-41; Ex. A, Boles Decl., at ¶¶ 9-11; *see also* Ex. H, Podraza Decl., at ¶¶ 5-6.) Indeed, numerous women regularly take progesterone during their first trimester who ultimately deliver healthy babies. (Ex. A, Boles Decl., at ¶¶ 10, 14; Ex. F, Hurm Decl., at ¶19; Ex. G, Dunavant Decl., ¶ 28.)

E. Case History

Plaintiffs—abortion clinics and one physician who performs abortions—filed a Complaint on August 31, 2020, challenging the informed-consent provision of the Act. (*See generally* D.E. 1.) They allege that the informed-consent provision compels them, their physicians, and their staff, to communicate a message they otherwise would not recite, in violation of the First Amendment. (D.E. 1, PageID# 24.) They also allege that the informed-consent provision violates their patients' substantive due process rights under the Fourteenth Amendment "by forcing them to receive information" that they claim "is untruthful, misleading, and/or irrelevant to the decision to have an abortion, that provides no benefit, . . . and that exposes them to potential harm." (D.E. 1, PageID# 24–25.) Finally, Plaintiffs allege that the informed-consent provision violates their and their patients' rights under the Equal Protection Clause of the Fourteenth Amendment. (D.E. 1, PageID# 25.) On September 1, 2020, the day after they filed their complaint, Plaintiffs moved for a temporary restraining order and/or preliminary injunction "enjoining enforcement of Tenn. Code Ann. § 39-15-218[.]" (*See generally* D.E. 4.)

ARGUMENT

The preliminary relief Plaintiffs are seeking is an "'extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion." *Glowco*, 958 F.3d at 539 (emphasis in original) (quoting *Mazurek*, 520 U.S. at 972). To determine whether such extraordinary relief is warranted, courts consider four factors: "(1) whether the

movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury absent the injunction; (3) whether the injunction would cause a substantial harm to others; and (4) whether the public interest would be served by the issuance of an injunction." *Am. Civil Liberties Union Fund of Mich. v. Livingston Cty.*, 796 F.3d 636, 642 (6th Cir. 2015). Because Plaintiffs have not made the requisite clear showing that they are entitled to preliminary relief, their motion for a temporary restraining order and/or preliminary injunction should be denied.

I. Plaintiffs Are Unlikely to Succeed on the Merits.

A. Plaintiffs lack standing to assert the rights and interests of their patients.

In Counts II and IV of their Complaint, Plaintiffs assert constitutional claims on behalf of their patients. Plaintiffs, however, lack third-party standing to assert the rights and interests of their patients because the informed-consent provision does not interfere with patients' right to obtain an abortion.

Generally, "one may not claim standing. . . to vindicate the constitutional rights of [a] third party." *Barrows v. Jackson*, 346 U.S. 249, 255 (1953). Although the Supreme Court has previously held that physicians and abortion clinics may assert the rights of their patients, standing has only been conferred where plaintiffs have challenged "governmental interference with the abortion decision." *Singleton v. Wulff*, 428 U.S. 106, 118 (1978); *see also Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833 (1992). Here, the challenged law does not hinder patients from obtaining an abortion. Instead, it merely provides patients with additional information about

the abortion procedure itself and advises them about the availability of potential remedies should they change their mind between taking the first and second abortion pill.

It is clear from their complaint that the Plaintiffs—physicians and abortion clinics—believe that the challenged law is unconstitutional and that it allegedly harms them and their patients. But what about the patients themselves? Even if some individual patients had a right to not receive the information contained in the disclosure required by the challenged law, those patients may not wish to challenge the law, instead preferring to receive all possible information regarding their abortion procedure. *See Singleton*, 428 U.S. at 113. Given this potential for divergence between the Plaintiffs' arguments and their patients' interests, the patients themselves are the best positioned to advocate for their interests and their rights, should they choose to assert them. *See id.*

The patient declarations attached as exhibits to this response confirm that not all abortion patients would necessarily support Plaintiffs' legal arguments. One declarant, Sarah Hurm, "feel[s] like the possibility to reverse your abortion needs to be told to all women and [she is] thankful that states like Tennessee are taking steps to ensure women know their full options." (Ex. F, Hurm Decl. at ¶ 23.) She "would have loved to have been given information that the Abortion Pill Reversal was there." (*Id.*) Carrie Beth Dunavant, a Tennessee resident who is pro-choice, also supports Tennessee's law. (Ex. G, Dunavant Decl., at ¶¶ 38–39.) She "think[s] the requirement that abortion providers tell mothers that they may be able to reverse the abortion procedure if they don't take the second pill gives women more options." (*Id.* at ¶ 38.) In her words, "[t]o be truly pro-choice, you have to allow women to know their options so they can make an informed choice." (*Id.*) Because of this clear divergence between Plaintiffs' interests and those

of their patients, third-party standing allowing Plaintiffs to vindicate the rights and claims of all of their patients is inappropriate.

Accordingly, Plaintiffs should not be permitted to assert any alleged interests, harms, or claims of their patients because Plaintiffs lack third-party standing to do so.

B. The Informed-Consent Provision is Constitutional.

1. The Informed-Consent Provision Does Not Violate the First Amendment.

"The principle that informed-consent requirements may be created by law, as opposed to merely medical-profession custom, applies to all medical procedures, including abortion." *EMW Women's Surgical Center, P.S.C., v. Beshear*, 920 F.3d 421, 437 (6th Cir. 2019). Still, Plaintiffs claim that the required disclosure is compelled speech that violates their First Amendment rights. But "the First Amendment has a limited role to play in allowing doctors to avoid making truthful mandated disclosures related to informed consent." *EMW*, 920 F.3d at 428. And for that reason, "'regulations of professional conduct that incidentally burden speech' receive lower scrutiny,'" *Id.* (quoting *Nat'l Inst. Of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2373 (2018) ("*NIFLA*")).

Accordingly, the Sixth Circuit has created the following test to determine whether an informed-consent statute is subject to heightened First Amendment scrutiny:

> Under the First Amendment, we will not highly scrutinize an informed-consent statute, including one involving informed consent to an abortion, so long as it meets these requirements: (1) it must relate to a medical procedure; (2) it must be truthful and not misleading; and (3) it must be relevant to the patient's decision whether to

> undertake the procedure, which may include, in the abortion context, information relevant to the woman's health rights, as well as the impact on the unborn life.

EMW, 920 F.3d at 428–29 (citing *NIFLA*, 138 S. Ct. at 2373; *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 882 (1992)). In reaching this conclusion, the Sixth Circuit relied on *Planned Parenthood of Minn., N.D., S.D. v. Rounds*, 530 F.3d 724 (8th Cir. 2008) (en banc), which held:

> *Casey* and *Gonzales* establish that, while the State cannot compel an individual simply to speak the State's ideological message, it can use its regulatory authority to require a physician to provide truthful, non-misleading information relevant to a patient's decision to have an abortion, even if that information might also encourage the patient to choose childbirth over abortion. *Therefore, Planned Parenthood cannot succeed on the merits of its claim that [the statute] violates a physician's right not to speak unless it can show that the disclosure is either untruthful, misleading, or not relevant to the patient's decision to have an abortion.*

Rounds, 530 F.3d at 734–35 (citing *Casey*, 505 U.S. 833; *Gonzales v. Carhart*, 550 U.S. 124 (2007)). Here, because the informed-consent provision relates to a medical procedure, is truthful and not misleading, and is relevant to the patient's decision to follow through with a medication abortion, the challenged provision does not violate the First Amendment.

i. The Informed-Consent Provision relates to a medical procedure.

The informed-consent provision "relates to a medical procedure" because it requires abortion providers to provide patients with information about the efficacy of a medication abortion. This is critical because a medication abortion, unlike a surgical abortion, does not occur in one step. A patient who consents to an abortion and takes the first pill is instructed to later take the second pill to complete the procedure. But what if she changes her mind? Certainly, a patient is permitted to withdraw her consent and refuse treatment. *See Cruzan by Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 270 (1990) ("The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment."); *see also* 1 Am. Law Med. Malp. § 4:12, Limitation or Withdrawal of Consent (July

2020 Update) (compiling state-court cases holding that patients may withdraw consent while a medical procedure is still in progress).

Relying on *NIFLA*, Plaintiffs argue that the required disclosures "relate to an entirely different and medically unsupported treatment—medication abortion 'reversal'—that Plaintiffs do not provide and that their patients are not seeking." (D.E. 6, PageID# 68.) This is a red herring. In *NIFLA*, the Court struck down a California law that required crisis pregnancy centers to inform women about the availability of state-subsidized contraception, prenatal care, and abortion services. 138 S. Ct. at 2369. But the Court did not hold, as Plaintiffs suggest, that the state-mandated notice failed to "relate to a medical procedure" simply because it required clinics to inform patients about medical procedures they did not provide. On the contrary, the Court explained that the California law "is not tied to a procedure at all" and instead "applies to all interactions between a covered facility and its clients, regardless of whether a medical procedure is ever sought, offered, or performed." *Id.* at 2373–74.

Unlike the California law in *NIFLA*, the informed-consent provision here is clearly tied to a medical procedure—medication abortion. The required disclosures inform patients about the efficacy of that procedure when a patient takes mifepristone but not misoprostol. While Plaintiffs may not agree with a patient's attempt to save her pregnancy, it is clear that the informed-consent provision relates to the consequences and options available if that patient withdraws her consent to a medication abortion before taking the second pill.

ii. The Informed-Consent Provision is truthful and not misleading.

Plaintiffs' principal argument is that they believe abortion reversal is a scientifically unsupported theory. But "[w]hen Congress undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad and courts should be cautious

not to rewrite legislation, even assuming, arguendo, that judges with more direct exposure to the problem might make wiser choices." *Marshall v. United States*, 414 U.S. 417, 427 (1974). So too here: "disagreements among medical professionals 'do not tie the State's hands in setting the bounds of . . . laws. In fact, it is precisely where such disagreement exists that legislatures have been afforded the widest latitude.'" *Stenberg v. Carhart*, 530 U.S. 914, 970 (2000) (Kennedy, J., dissenting) (quoting *Kansas v. Hendricks*, 521 U.S. 346, 360, n.3 (1997)); *see also Collins v. Texas*, 223 U.S. 288, 297–98 (1912) (Holmes, J.) (declaring "the right of the state to adopt a policy even on medical matters concerning which there is a difference of opinion and dispute"); *Lambert v. Yellowley*, 272 U.S. 581, 596–97 (1926) (rejecting claim of distinguished physician because "[h]igh medical authority being in conflict . . . it would, indeed, be strange if Congress lacked the power [to act]."); *Marshall*, 414 U.S. at 427 (recognizing "there is no agreement among members of the medical profession").

The Sixth Circuit has been similarly deferential to the state in the context of informed consent. The Sixth Circuit, for example, has held that "certain medical groups' views regarding whether a particular mandated truthful disclosure is necessary for informed consent—is not the type of evidence deemed material by the Supreme Court in reviewing abortion-informed-consent statutes." *EMW*, 920 F.3d at 428. To reach this conclusion, the Sixth Circuit noted that in both *Casey* and *Gonzalez*, the Supreme Court's holdings permitting content-based informed consent and a ban on partial birth abortion was contrary to the official positions of ACOG and the American Public Health Association. *See id.* at 438. The Sixth Circuit expressly rejected Plaintiffs' argument "that we 'must naturally turn to the medical community' to ascertain the 'contours of informed consent' to determine whether a regulation is in accord with 'medical practice' or 'medical purpose.'" *Id.* at 439 (quoting Donald, J., dissenting). The relevant consideration here

is whether the informed-consent provision is truthful and not misleading—not whether certain medical groups, physicians, or customs agree with it. *See id.* at 439 (citing *Canterbury v. Spence*, 464 F.2d 772, 784, 787 (D.C. Cir. 1972)).

a. The signage and written discharge instructions are truthful and not misleading.

The signage and written discharge instructions required by subsections (b) and (f) include the following statement:

> Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately.

Tenn. Code Ann. § 39-15-218(b) and (f).

There is no doubt that these statements are truthful and not misleading. It is undisputed that taking mifepristone alone is not always effective at ending a pregnancy. In their Complaint, Plaintiffs admit that "[m]edication abortion is more effective when both mifepristone and misoprostol are used together because *mifepristone alone will not always cause an abortion*." (D.E. 1, PageID# 19.) (emphasis added). In fact, Dr. Daniel Grossman, an abortion provider, surveyed 13 different studies and found that between 8% and 46% of pregnancies will continue when only mifepristone is administered.[2] (*See* Schreiber Decl., D.E. 6-1, PageID# 179; *see also* Ex. __, Boles Decl., at ¶ 6; Ex. __, Harrison Decl., at ¶ 9; Ex. __, Delgado Decl., at ¶ 24.) Indeed, Planned Parenthood itself admits that "[s]tudies on the abortion pill do show that if you take the first medicine but not the second, the abortion pill is less likely to work. So if you've begun the process of having an abortion using the abortion pill but are having second thoughts, contact the doctor or nurse you saw for the abortion right away to talk about your best next steps and what to

[2] Dr. Delgado conservatively estimates the number to be 25%. (Ex. D, Delgado Decl., at ¶ 24.)

expect." (Ex. C, Dunne Decl.) Accordingly, the first drug, mifepristone, when taken alone without misoprostol, "is not always effective in ending a pregnancy." Tenn. Code Ann. § 39-15-218(e). And as mifepristone may not end a pregnancy without misoprostol, as Planned Parenthood concedes, it follows that "[i]t *may* be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken." *See id.* § 39-15-218(b).

Plaintiffs may disagree with the use of progesterone to save a pregnancy, but there is no question that the signage and discharge informed-consent requirements in subsections (b) and (f), which are wholly grounded in the fact that mifepristone may not end a pregnancy without misoprostol, are truthful and not misleading.

b. The physician informed-consent requirement is truthful and not misleading.

The physician informed-consent requirement requires the following language:

> (1) It may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind, but that time is of the essence; and
>
> (2) Information on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website.

Tenn. Code Ann. § 39-15-218(e).

The statement in (1) is certainly true. As a threshold matter, the physician informed-consent requirement promises nothing: it only discloses that it "may be possible" to save a pregnancy. For Plaintiffs to succeed in their argument that the statement is untrue, they must demonstrate that it is entirely *im*possible to reverse "the *intended effect* of a chemical abortion utilizing mifepristone"—that is, to terminate a pregnancy. They cannot carry this heavy burden.

First, simply not taking the second pill of misoprostol may reverse the "*intended effects* of a chemical abortion utilizing mifepristone." As discussed above, Planned Parenthood concedes

that if only mifepristone is taken, it may not be sufficient to terminate the pregnancy. Thus, not taking misoprostol may save the pregnancy and may indeed reverse the *intended effects* of the medication abortion.

This is an important distinction: the physician informed-consent requirement does not state that mifepristone is reversed by progesterone. Nor does it state that an abortion itself can be reversed. Instead, it states that it may be possible that the *intended effect* of a chemical abortion may be reversed—that is, that the intended termination of pregnancy may not occur. While Plaintiffs will point this Court to *American Medical Association v. Stenehjem*, 412 F.Supp.3d 1134, (D. N.D. 2019) in support of their argument, a review of the North Dakota disclosure reveals meaningful distinctions. Where North Dakota required a statement that "it may be possible to reverse the effects of an abortion-inducing drug," Tennessee is different, only requiring a statement that "it may be possible to reverse the *intended* effects of a chemical abortion utilizing mifepristone." *Compare id.* at 1138 *with* Tenn. Code Ann. § 39-15-218(e)(1) (emphasis added). And not taking misoprostol may well preserve a pregnancy.[3]

Regardless, the record here demonstrates that scientific and anecdotal evidence supports the use of progesterone to increase the chances of saving a pregnancy. (*See generally, supra* Section D.; Ex. B, Harrison Decl., at ¶¶ 8-32; Ex. D, Delgado Decl., at ¶¶ 17-24; Ex. A, Boles

[3] The District Court of North Dakota's decision is also distinguishable in other ways. To determine whether North Dakota's law was misleading or truthful, the court relied largely upon the plaintiffs' experts because "[t]he Court was unaware of any federal case that supports the argument that, even if a medical debate exists, a state legislature is free to take sides in a medical debate." *AMA*, 412 F.3d at 1151. The Sixth Circuit in *Beshear*, however, disagreed "that we 'must naturally turn to the medical community' to ascertain the 'contours of informed consent' to determine whether a regulation is in accord with 'medical practice' or 'medical purpose.'" *Beshear*, 920 F.3d. at 439 (quoting Donald, J., dissenting). In this Circuit, then, the relevant consideration is whether the informed-consent provision is truthful and not misleading—not whether certain medical groups, physicians, or customs agree with it. *See id.* at 439 (citing *Canterbury v. Spence*, 464 F.2d 772, 784, 787 (D.C. Cir. 1972)).

Decl., at ¶¶ 8-14.) For example, Dr. Delgado's 2018 study found that that the use of progesterone after a woman takes mifepristone resulted in a rescued pregnancy about 68% of the time. Plaintiffs offer *no* countervailing research that proves it is *impossible* for progesterone to counteract the effects of mifepristone. Instead, Plaintiffs raise inadequate complaints about the methodology of Dr. Delgado's study, all of which are thoroughly addressed and rebutted by Dr. Harrison. (Ex. B, Harrison Decl., at ¶¶ 33-43.)

Additionally, the State has offered proof from two Tennessee practitioners of abortion pill reversal as well as two patients who successfully received APR treatment. (Ex. A, Boles Decl.; Ex. H, Podraza Decl.; Ex. G, Dunavant Decl.; Ex. F, Hurm Decl.) This anecdotal evidence further supports the State's position that progesterone *may* be able to reverse the intended effects of a medication abortion—just as taking mifepristone alone, without taking progesterone, *may* be sufficient to avoid, cease, or even reverse the intended effects of that abortion-inducing drug. And while Plaintiffs strain to cast doubt on these studies and their practical results by attacking the methodology and conclusions regarding progesterone use, nothing in their motion demonstrates that it is entirely *impossible*—an important distinction, as it is their burden to disprove that "it *may* be possible to reverse the *intended* effects of a chemical abortion utilizing mifepristone." (*see, e.g,* Ex. I, Creinin Study ("[w]e should not dismiss mifepristone antagonization as impossible…the "evidence is inadequate to support *or refute* the benefits and risks of any treatment.") (emphasis added).

And as for the statement in (2), Plaintiffs make no argument that the required information will not be available on the department of health website on the date the law becomes effective. Accordingly, the physician informed-consent requirement is truthful and not misleading.

iii. The Informed-Consent Provision is relevant to the patient's decision to continue the medication abortion.

Plaintiffs maintain that the informed-consent provision is irrelevant to the patient's decision to have an abortion. (D.E. 6, PageID# 73.) But they neglect the fact that a medication abortion is a two-step process—after all, as discussed above, mifepristone alone may not be successful in terminating a pregnancy. For patients who may change their mind about their decision after taking the first pill, the informed-consent provision is highly relevant to their decision to continue the abortion procedure and take the misoprostol. And while Plaintiffs dismiss this information as irrelevant, for a patient who does wish to save their pregnancy, this information is of the utmost relevance. Indeed, it may be an ethical violation to not provide this information to patients. (Ex. A, Boles Decl., at ¶16, citing American Medical Association's Code of Ethics in sections 1.1.1 and 1.1.3 that require the physician treating the patient to give an accurate and complete disclosure of information in the informed consent process and to do so in a manner that it is not self-serving to the physician's own interests).

What is more, Defendants do not ask this Court to evaluate the relevance of this provision in the abstract. For Ms. Hurm and Ms. Dunavant, the disclosure was highly relevant to their decision not to continue their abortions by taking misoprostol. Yet neither of them received this information from their physicians—they were forced to hunt for the information online. (Ex. F, Hurm Decl., at ¶ 15–16; Ex. G, Dunavant Decl., at ¶ 20, 24.) Ms. Hurm and Ms. Dunavant evidently found this information relevant to their determination not to continue the medication abortion procedure, as both chose not to take the misoprostol and instead sought progesterone supplements to successfully save their pregnancies. (Ex. F, Hurm Decl., at ¶ 16–19; Ex. G, Dunavant Decl., at ¶ 20–24.) And both believe that this option would be relevant to other patients' ability to choose whether or not to continue their medication abortions. (Ex. F, Hurm Decl., at ¶ 13, 23; Ex. G, Dunavant Decl., at ¶ 38.)

Lastly, while Plaintiffs make much of the signage requirement, arguing that it could be read by patients seeking a surgical abortion, one can reasonably assume that surgical abortion patients are capable of understanding that information about medication abortion does not apply to them. And if Plaintiffs truly do contend that a patient undergoing a surgical abortion may be misled into thinking that their pregnancy could be saved, they have done a poor job in explaining the surgical abortion procedure.

C. The Informed-Consent Provision Satisfies Rational Basis Review.

Here, it is evident that the informed-consent provision easily satisfies rational-basis review. Under rational-basis review, a law is presumed constitutional, and "[t]he burden is on the one attacking the legislative arrangement to negate every conceivable basis which might support it." *Heller v. Doe*, 509 U.S. 312, 320 (1993) (internal quotations omitted); *see also Walker v. Bain*, 257 F.3d 660, 668 (6th Cir. 2001) (stating that a statute is subject to a "strong presumption of validity" under rational-basis review and will be upheld "if there is any reasonably conceivable state of facts that could provide a rational basis").

A court conducting a rational-basis review does not sit "as a super legislature to judge the wisdom or desirability of legislative policy determinations" but asks only whether there is some conceivable rational basis for the challenged statute. *Heller*, 509 U.S. at 319. This means that under rational-basis review, it is "'constitutionally irrelevant [what] reasoning in fact underlays the legislative decision.'" *R.R. Ret. Bd. v. Fritz*, 449 U.S. 166, 179 (1980) (quoting *Flemming v. Nestor*, 363 U.S. 603, 612 (1960)). In enacting the informed-consent provision, the General Assembly and the citizens of Tennessee had "absolutely no obligation to select the scheme" that a court might later conclude was best. *Nat'l R.R. Passenger Corp. v. A.T. & S.F.R. Co.*, 470 U.S. 451, 477 (1985); *see McGowan v. Maryland*, 366 U.S. 420, 425–426 (1961) ("State legislatures

are presumed to have acted within their constitutional power despite the fact that in practice, their laws result in some inequality."). And Tennessee "has no obligation to produce evidence to sustain the rationality of its action; its choice is presumptively valid and 'may be based on rational speculation unsupported by evidence or empirical data.'" *TriHealth, Inc. v. Bd. of Comm'rs*, 430 F.3d 783, 790 (6th Cir. 2005) (quoting *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993)).

Here, the rational basis for the informed-consent provision is readily apparent. Tennessee certainly has "legitimate interests in protecting both 'the health of the woman and the life of the fetus that may become a child.'" *Planned Parenthood Cincinnati v. Taft*, 444 F.3d 502, 508 (6th Cir. 2006) (quoting *Casey*, 505 U.S. at 846). Tennessee's informed-consent provision rationally furthers those interests by providing patients with information about the consequences and options should they choose not to continue their medication abortion, thus facilitating the wise exercise of the right to abortion and providing the patient with direction should they wish to try to save their pregnancy. *See Casey*, 505 U.S. at 887.

The best illustrations of the State's interests in preserving fetal life and providing better informed consent are the stories of patients who changed their mind and decided not to continue their abortion after taking mifepristone. Sarah Hurm is a single mom in Iowa who wishes she had known about the possibility of reversing the first abortion pill before her 2018 abortion attempt. (Ex. F, Hurm Decl., at ¶ 23.) After taking the first abortion pill at Planned Parenthood, she "went home and cried." (*Id.* at ¶ 15.) She regretted the decision and "search[ed] the internet for ways to undo the effects of the pill." (*Id.* at ¶ 15–16.) After finding Abortion Pill Rescue, she was able to get in with a doctor the next day who prescribed her progesterone, and her son Isaiah was born in 2019 "healthy and perfect." (*Id.* at ¶ 16, 19.) Abortion pill reversal saved her son, who is "everything [she] needed, before [she] even knew it." (*Id.* at ¶ 19, 21.) Ms. Hurm "would

have loved to have been given information" about abortion pill reversal before her abortion. (*Id.* at ¶ 23.) She admits that when she went to Planned Parenthood to get an abortion, she didn't know how the pills "actually worked," and she appreciates that "states like Tennessee are taking steps to ensure women know their full options." (*Id.* at ¶ 13, 23.)

Tennessee resident Carrie Beth Dunavant has a similar story. She found out she was pregnant in 2016, and for a variety of reasons, decided to have an abortion. (Ex. G, Dunavant Decl., at ¶ 2, 3–9.) But as soon as she got to her car in the parking lot of Planned Parenthood, she regretted her decision. (*Id.* at ¶ 18.) She was not told that reversal was an option or even possible; so, she panicked, leading to "the lowest possible feeling [she has] ever experienced." (*Id.* at ¶ 15, 17.) Luckily, an internet search led her to the Abortion Pill Rescue hotline, and she was connected with a doctor that started her on progesterone. (*Id.* at ¶ 20, 24.) As she describes it, she "suffered a lot in those hours of self-loathing and regret" before she learned that she may be able to stop the abortion, and the nurse who told her about the possibility "changed [her] life." (*Id.* at ¶ 23, 37.) That information gave Ms. Dunavant "hope and love when [she] felt like [she] had nothing else and didn't deserve anything because of what [she] had done." (*Id.* at ¶ 23.) Ms. Dunavant is pro-choice, and feels that Tennessee's informed-consent provision "allow[s] women to know their options so they can make an informed choice." (*Id.* at ¶ 38.) After learning of the possibility of reversing her abortion, Ms. Dunavant made the "informed choice" to continue her pregnancy and she is now the proud mother of Cameron. (*Id.* at ¶ 28.)

The experiences of these two women provide real-world examples of the rational basis for the law. (*See also* Ex. H, Podraza Decl., at ¶ 6.) They reveal how Tennessee's informed-consent provision can rationally further the State's interests in maternal health and fetal life by providing patients with information about the consequences and options should they choose not to continue

their medication abortion. In other words, the provision facilitates the wise exercise of the right to abortion, *see Casey*, 505 U.S. at 887, and should be upheld under the rational-basis standard.

Plaintiffs seek to escape this conclusion by attempting to invoke strict scrutiny for their equal protection claims (Counts III and IV), arguing that the informed-consent provision "interferes with the exercise of the fundamental right to abortion." (D.E. 6, PageID# 75, n.14.) But strict scrutiny is not appropriate here. It is well settled that "abortion is a unique act." *Casey*, 505 U.S. at 852. It is "an act fraught with consequences for others: for the women who must live with the implications of her decision; for the persons who perform and assist in the procedure"; and "for the spouse, family, and society which must confront the knowledge that these procedures exist." *Id*.

In *Casey*, the Supreme Court expressly rejected the strict scrutiny analysis applied in *Roe* in favor of the undue burden analysis. *See* 505 U.S. at 872–76. Since then, courts have repeatedly recognized that both equal protection and substantive due process claims are subsumed into the undue burden test. *See, e.g.*, *Tuscon's Woman's Clinic v. Eden*, 379 F.3d 531, 544–45 (9th Cir. 2004); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 172–73 (4th Cir. 2000); *Planned Parenthood of Mid-Missouri and E. Kan., Inc. v. Dempsey*, 167 F.3d 458, 464 (8th Cir. 1999). And in any event, because the informed-consent provision merely provides a patient with additional truthful, non-misleading information and creates no barriers to the exercise of the right to an abortion, strict scrutiny is simply not appropriate.

And even if the informed-consent provision was subject to the undue burden framework, as opposed to the standard set forth by the Sixth Circuit in *Beshear*, it would still pass constitutional muster. Under the undue burden framework, a law may be invalidated when it acts as a "substantial obstacle to a woman's choice to undergo an abortion" "in a large fraction of cases in

which [it] is relevant." *Casey*, 505 U.S. at 925. There is no right to abortion on demand, *Casey*, 505 U.S. 822; *Taft*, 444 F.3d 502, and the informed-consent provision does not burden or interfere with the ultimate decision to have an abortion—it simply provides for a non-coercive, accurate disclosure of a patient's available options should they decline to continue their abortion after taking mifepristone. And as discussed *infra*, a physician retains the ability to place that disclosure in context and elaborate upon (or advocate against) it in the manner best suited to each patient's individual needs. The choice remains the patient's, and therefore the informed-consent provision would also satisfy the undue burden standard.

D. The Informed-Consent Provision is Not Expressive or Ideological Speech.

Plaintiffs next try to invoke heightened First Amendment scrutiny. But that is likewise inappropriate because the informed-consent provision is neither ideological nor expressive speech. Ideological speech is speech which conveys a "point of view." *Wooley v. Maynard*, 430 U.S. 705, 715 (1977). A statement of fact does not necessarily communicate an ideological or political message. "Informing a patient that there are state-issued materials available is not ideological, because the viewpoint conveyed by the pamphlet is clearly the state's—not the physicians." *Stuart v. Camnitz*, 774 F.3d 238, 253 (4th Cir. 2014).

"[W]hile the State cannot compel an individual simply to speak the State's ideological message, it can use its regulatory authority to require a physician to provide truthful, non-misleading information relevant to a patient's decision to have an abortion, even if that information might also encourage the patient to choose childbirth over abortion." *Rounds*, 530 F.3d at 734–35. Thus, "under *Casey*, what matters for First Amendment purposes is whether the disclosed facts are truthful, non-misleading, and relevant to the procedure, not whether they fall on one side of the debate, and not whether they influence a woman to keep the child." *Beshear*, 920 F.3d at

435–36 (citing *Casey*, 505 U.S. at 882–84; *Lakey*, 667 F.3d at 575–77; *Rounds*, 530 F.3d at 734–35).

In *Beshear*, despite objections by abortion providers and clinics, the Sixth Circuit rejected an argument that an ultrasound requirement was ideological and declined to adopt a broad view of what constitutes ideological speech in the abortion context. *Beshear*, 920 F.3d at 435–36. So too here. The informed-consent provision does not require physicians to agree with it, nor does it prevent them from disclosing to the patient that the state requires them to make that statement. Thus, like the ultrasound requirement in *Beshear* and the informed-consent requirement in *Casey*, Tennessee's informed-consent provision is not compelled ideological or expressive speech.

E. The Informed-Consent Provision Does Not Interfere with the Physician-Patient Relationship.

In their quest to invoke heightened scrutiny, Plaintiffs also argue that the informed-consent provision impermissibly interferes with the physician-patient relationship. But "informed consent is generally required for medical treatment." *Id.* at 428 (quoting *Cruzan*, 497 U.S. at 269). "[T]he common-law doctrine of informed consent is viewed as generally encompassing the right of a competent individual to refuse medical treatment." *Id*. (quoting *Cruzan*, 497 U.S. at 277). "This right, grounded in principles of self-determination, may 'demand[] a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.'" *Id.* (quoting *Canterbury v. Spence*, 464 F.2d 772, 784 (D.C. Cir. 1972)); *see also* F. Rozovsky, Consent to Treatment: A Practical Guide 2–8 (5th ed. 2018) ("explaining that informed-consent standards are set by 'state legislation, regulations, and case law' in addition to standards among professional groups.") (footnote omitted). "[T]o safeguard the patient's interest in achieving [her

or] his own determination on treatment, the law must itself set the standard for adequate disclosure." *Id.* (quoting *Canterbury*, 464 F.2d at 787) (alteration in original).

The principle that informed-consent provisions may be created by law "applies to all medical procedures, including abortion." *Beshear*, 920 F.3d at 437. "If the validity of an informed consent law depended on whether doctors agreed with the law—or whether the law required disclosures that, with no law, the doctor would disclose anyway—there would be no need for the law to supplement custom." *Id.* at 439 (citing *Canterbury*, 464 F.2d at 784.)

Here, Plaintiffs claim that the informed-consent provision undermines the trust patients place in their physicians and impedes patients' ability to make informed healthcare decisions. But again, physicians retain the power to inform their patients that the disclosure is required by the state, and that they disagree with it. *See Beshear*, 920 F.3d 439 (citing *Rust v. Sullivan*, 500 U.S. 173, 200 (1991) ("Nothing requires a doctor to represent as his own any opinion that he does not in fact hold"); *Fargo Women's Health Org. v. Schafer*, 18 F.3d 526, 534 (8th Cir. 1994) (upholding abortion-informed-consent statute and observing that it allowed doctors to 'disassociate themselves' from the required information).

Because the informed-consent provision "operate[s] to allow a doctor who reasonably believes that the disclosures would result in a severely adverse effect on the patient[] to inform the patient in the doctor's discretion that she need not listen to or view the disclosures," it does not diminish the physician-patient relationship. *See Beshear*, 920 F.3d at 440.

F. The Informed-Consent Provision Also Survives Heightened Scrutiny.

Even if the informed-consent provision was subject to heightened scrutiny, it would still survive. A regulation will survive heightened scrutiny when: (1) the regulation "is within the constitutional power of Government;" (2) "it furthers an important or governmental interest;" (3)

"the governmental interest is unrelated to the suppression of free expression;" and (4) "the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest." *United States v. O'Brien*, 391 U.S. 367, 376 (1968). The informed-consent provision satisfies these four elements.

The informed-consent provision is "within the Constitutional power of Government" and further an "important" interest. *See id.* It is well settled that States have the power to regulate the medical profession and even to create informed-consent laws that differ from those preferred by the medical community. *See Beshear*, 920 F.3d at 437 (explaining that "[i]f the validity of an informed consent law depended on whether doctors agreed with the law—or whether the law required disclosures that, with no law, the doctor would disclose anyway—there would be no need for the law to supplement custom"). And, as discussed above, Tennessee—like all states—has "legitimate interests in protecting both 'the health of the woman and the life of the fetus that may become a child.'" *See Taft*, 444 F.3d at 508 (6th Cir. 2006) (quoting *Casey*, 505 U.S. at 846). Tennessee's informed-consent provision furthers those interests by providing patients with information about the consequences and options should they choose not to continue their medication abortion, thus facilitating the wise exercise of the right to abortion and providing the patient with direction should they wish to try to save their pregnancy. *See Casey*, 505 U.S. at 887.

Further, these government interests—maternal health and fetal life—are "unrelated to the suppression of free expression." *See O'Brien*, 391 U.S. at 376. Instead, both interests stem from the desire to protect human life. Any restrictions on First Amendment freedoms stemming from the informed-consent provision are "incidental" and are "no greater than is essential to the furtherance of [the State's] interest[s]." *See id.* The informed-consent provision mandates only that physicians provide their patients with a complete picture by informing them of the possibility

of reversing the effects of a medication abortion should they choose to do so. The informed-consent provision goes no further—the physicians subject to the requirements retain the power to inform their patients that the disclosure is required by the state, and that they disagree with it. *See Beshear*, 920 F.3d 439 (citing *Rust v. Sullivan*, 500 U.S. 173, 200 (1991) ("Nothing requires a doctor to represent as his own any opinion that he does not in fact hold.").

Lastly, unlike the North Dakota law struck down in *Stenehjem*, 412 F.Supp.3d at 1134, Tennessee's informed-consent language here need only be given to patients undergoing a chemical, as opposed to surgical abortion. *See* Tenn. Code Ann. § 39-15-218(e). And the signage informed-consent requirement's plain language makes clear that it is applicable only to chemical abortions. *See* Tenn. Code Ann. § 39-15-218(b). Accordingly, the informed-consent provision is sufficiently tailored to survive heightened scrutiny.

In sum, the informed-consent provision furthers the State's well-established interests in maternal health and fetal life. And it furthers those interests in a manner unrelated to the suppression of free expression. Thus, even if the informed-consent provisions were properly subject to heightened scrutiny, it would easily survive.[4]

II. Plaintiffs are unlikely to suffer irreparable injury absent the injunction.

A plaintiff seeking preliminary injunctive relief must demonstrate that irreparable harm is likely in the absence of the requested injunction. *Los Angeles v. Lyons*, 461 U.S. 95, 103 (1983); *O'Shea v. Littleton*, 414 U.S. 488, 502 (1974). The showing of likely irreparable harm is the single most important prerequisite for issuance of a preliminary injunction. *See* 11A C. Wright, A. Miller, & M. Kane, Fed. Practice and Procedure § 2948.1 (3d ed.). Speculative injury is not sufficient. *Id.* A preliminary injunction is not warranted to prevent the possibility of some remote future

[4] And, even if they did not, the law contains an express severability clause.

injury—a presently existing actual threat must be shown. *Id.* "Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Mazurek*, 520 U.S. at 972.

Plaintiffs are all abortion clinics or providers who claim that enforcement of the informed-consent provision would constitute irreparable harm by allegedly depriving them of their First Amendment freedoms. (D.E. 6, PageID # 76.) They also claim that their patients face irreparable harm by allegedly "impeding informed consent, directing them to an unproven and potentially unsafe treatment, and undermining their trust in their healthcare providers." (D.E. 6, PageID# 76). But as discussed above, they have the ability to place the informed-consent provision's disclosure in whatever context they feel that would be most beneficial to the individual patient. *See Rust*, 500 U.S. at 200. They can simply inform the patient, as they likely will, that the law requires them to make this statement and that they disagree with it. That Plaintiffs retain the power to distinguish and disagree with the informed-consent language wholly mitigates their alleged First Amendment harms. And it is well settled that there is no constitutional right to perform abortions. *See Hodges*, 917 F.3d 908, 913 (6th Cir. 2019) (en banc).

As to their patients, Plaintiffs in this context do not possess third-party standing to assert their patients' interests, rights, or harms. *Supra* at 11-12. But even if Plaintiffs could, it strains credulity to argue that more information and better-informed consent is harmful to a patient. It is the patients' choice which controls the course of their medical treatment, *see Cruzan*, 497 U.S. at 273, 278, and assuming that patients are harmed by providing them additional information to understand the full implications and consequences of their decision discredits their autonomy.[5]

[5] And it must be noted that physicians suffer no harm when a patient changes their mind about

Further, if patients truly do not want to hear the disclosure, they are free to choose a surgical abortion instead of a medication abortion. *See Women's Medical Professional Corp. v. Taft*, 353 F.3d 436, 449–50 (6th Cir. 2003) (recognizing that there is no constitutional right to a particular method of abortion) (citing *Carhart*, 530 U.S. at 931).

At base, Plaintiffs' asserted harm is that they do not wish to inform their patients of the disclosure. But they are already required to give informed consent under Tennessee law. *See* Tenn. Code Ann. § 39-15-202. The two additional sentences hardly rise to the magnitude of irreparable harm. Plaintiffs' obstinance, standing alone, falls far short of irreparable harm necessary to justify the extraordinary relief of a preliminary injunction.

III. Issuance of an injunction would harm the State and the public interest.

An injunction that prevents a State from enforcing a duly enacted law necessarily irreparably harms the State. *See, e.g.*, *Abbott v. Perez*, 138 S. Ct. 2305, 2324 (2018); *Maryland v. King*, 133 S. Ct. 1, 3 (2012) (Roberts, C.J., in chambers) (citation omitted); *Detroit Newspaper Publisher Ass'n v. Detroit Typographical Union*, 471 F.2d 872, 876 (6th Cir. 1972), *cert. denied*, 411 U.S. 967 (1973); *MLZ, Inc. v. Fourco Glass Co.*, 470 F. Supp. 273, 278 (M.D. Tenn. 1978). And where the party opposing equitable relief is the government, consideration of the public interest "merge[s]" with irreparable harm to the government. *Nken v. Holder*, 556 U.S. 418, 435 (2009); *see also, e.g.*, *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). The public has a strong interest in laws duly passed by its representative branch of government, and thus the public interest and harm to the state militate against injunctive relief. *Abbott*, 734 F.3d at 419.

Issuance of an injunction would also harm the very patients that Plaintiff claim to

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their medical treatment.

represent. While Plaintiffs allege that "[a]mong our basic responsibilities as healthcare providers is to provide patients with clear, medically accurate, and relevant information so that they are able to make informed decisions about the medical treatment they are considering," (D.E. 6-5, PageID# 285), it is clear from their practice that this "responsibility" ends whenever the patient chooses not to continue the termination of their pregnancy. Just as a patient has a right to refuse or discontinue a course of treatment, *see, e.g.*, *Cruzan*, 497 U.S. at 273, 278, they have the right to choose not to take the second pill and pursue alternative options to save their pregnancy. Plaintiffs' practice of denying their patients information regarding alternatives should they in fact withdraw their consent to the medication abortion procedure is decidedly anti-choice. That they do not trust their patients to make the decision best for them and ignore the possibility of a change of heart needlessly disadvantages patients in a situation where—should they change their decision and not take the second pill—they may lack the information necessary to effectuate their change of mind and attempt to save their pregnancy.

And this concern is not merely hypothetical. Attached to this response are declarations of patients who began their abortion but changed their mind shortly after taking the first pill. (Ex. G, Dunavant Decl., at ¶ 18; Ex. F, Hurm Decl., at ¶¶ 15–16.) Each was forced to rely upon internet searches because their abortion providers did not inform them of their option to try and save their pregnancy. (Ex. G, Dunavant Decl., at ¶¶ 20, 24; Ex. F, Hurm Decl., at ¶¶ 15–16.) For them, and for others in similar circumstances, the required informed consent would have served a profound purpose by giving them guidance and support when they changed their mind. (Ex. G, Dunavant Decl., at ¶ 38; Ex. F, Hurm Decl., at ¶ 23; Ex. J, Shuping Decl.) These declarations ended happily—after choosing not to complete the medication abortion and by undergoing progesterone treatment, these patients were able to save their pregnancies. (Ex. G, Dunavant Decl., at ¶ 28; Ex.

F, Hurm Decl., at ¶¶ 16, 19.) But for others who continue the abortion process despite choosing otherwise—perhaps after their abortion providers withheld the options of not taking the second pill or seeking progesterone treatments or claimed that their child could be deformed if the second pill is not taken—the harm of losing their pregnancies after they changed their minds is palpable and truly irreparable. (*see* Ex. J, Shuping Decl.) Contrasted with Plaintiffs' failure to identify patients who would be meaningfully harmed by a mere disclosure, it is evident that the balance of harms weighs heavily against an injunction.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court deny Plaintiffs' motion for a temporary restraining order and/or preliminary injunction.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Response has been served on the following counsel of record through the Electronic Filing System on this 14th day of September, 2020:

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